

Applicant : Jian Bai, Steven M. Fischer and J. Michael Flanagan
Appl. No. : 10/806,829
Examiner : Nikita Wells
Docket No. : 10980322-4 (12089.4003)

RESPONSE

As noted in the previous Amendment and Response (1/22/08), this is a continuing application from application number 09/146,817 that was awarded priority of invention in Patent Interference No. 105,745 over USP 5,965,884 to inventor Victor Laiko. The present claims in this application were originally presented March 22, 2004 to provoke an interference with the issued claims in USP 6,683,300 to Doroshenko, Victor Laiko, Yakshin, Prasad and Sang Lee. The '300 patent is quite similar to the present application although the present application was filed many years after the priority date of the present application. The present application does not appear to have been considered as prior art in the prosecution of the '300 patent.

The pending claims recite a method for performing AP MALDI on a liquid-analyte solution and recite the element:

“without additional matrix added to said analyte solution.” See claims 34, 51, and 65.

This language describes performing MALDI on a sample analyte directly in solution such that the laser irradiates the solution and ionization of the analyte occurs by direct charge transfer from the irradiated solution to the analyte.

All prior art based objections have been resolved and the lone remaining issue is the adequacy of the written description under §112 for the claim element:

“irradiating a liquid volume of said analyte solution, without additional matrix added to said analyte solution...”

Because no doubt can exist that the present specification discloses the step of irradiating a liquid volume of analyte solution, the only remaining issue is the adequacy of support in the present specification for the element:

“without additional matrix added to said analyte solution”

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The Examiner has also noted in the last action that this element was the “key element” in the allowance of the ’300 patent.

A. The Present Specification Satisfies The Written Description Requirement of §112 For The Step of Irradiating a Liquid Analyte Solution Without Added Matrix

A careful review of the specification shows that an analyte solution without added matrix is clearly described in the present specification. First, the present specification discloses that the analyte contained in solution can be ionized by irradiating the solution itself. Where the analyte is ionized directly by the solution, no additional matrix is used. Second, the specification expressly defines the solution containing the analyte as an option for the “matrix” that facilitates ionization of the analyte. This occurs in the solution containing the analyte and occurs in the absence of “additional matrix” apart from the solution. Therefore, a description of the direct ionization of analyte in solution is a written description of the element at issue and description in the present specification meets the requirements of §112.

1. The law governing the written description requirement of §112

To adequately support the element of an analyte solution without added matrix, the law does not require that these terms appear verbatim in the specification. The purpose of the written description requirement is to confirm that the inventor “possesses” the invention as of the time of the application. In re Johnson, 558 F.2d 1008, 1018 (CCPA 1977).

The courts have uniformly held that a patent specification need not expressly disclose verbatim the linguistic formulation used in the claim. The proper focus of the inquiry is whether the specification adequately supplies formulas, charts, diagrams or any other material from

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which one skilled in the art can ascertain that the inventor “possessed,” or invented, the subject matter of the claim. As the court held in In re Smith, 481 F.2d 910 (CCPA 1973):

The specification as originally filed must convey clearly to those skilled in the art information that the applicant has invented the subject matter later claimed. [Citations omitted] When the original specification accomplishes that, regardless of how it accomplishes it, the essential goal of the description requirement is realized.

“The written description requirement is satisfied by the patentee’s disclosure of ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’” Crown Operations International Ltd. V. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002). For purposes of the written description requirement, the invention may be described by words, figures, diagrams or formulas. Crown Operations International Ltd. V. Solutia Inc., 289 F.2d 1367, 1376 (Fed. Cir. 2002).

2. The specification describes a liquid analyte solution that is irradiated to yield ionized analyte.

The disclosure and embodiments of the present specification that describe the liquid analyte solution without additional matrix include:

“Flowing” refers to a liquid sample or matrix which is moving and from which the sample and matrix is analyzed.

(See specification page 10, lines 20 – 21 and here after “Spec 10:20 – 21”)

“Holder” also refers to an interface for introducing a moving liquid e.g. the effluent from a HPLC or CE a syringe pump and the like.

(Spec 10:25-27)

The analyte matrix may be a liquid such as water or alcohol e.g. methanol, or a solid such as ice.

(Spec 13:2–3)

The sampling may occur using a static or a flowing liquid sample, such as the effluent from an HPLC, CE, or syringe pump.

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(Spec 13:8-10)

These examples disclose the liquid containing the analyte, and it is this liquid that is irradiated to generate the ionized analyte. No requirement for any added matrix exists and none is described.

Thus, when the present specification discloses irradiation of a flowing liquid solution containing analyte, the specification is describing an analyte solution without added matrix because the solution transfers charge to (or from) an analyte, and thereby, acts as the matrix.

3. The definition of “Matrix” includes a liquid solution containing analyte that has no “additional matrix.”

The present specification does not require that any matrix be added to the analyte solution. The present specification defines “matrix” as:

“Matrix” refers to any solid or liquid molecules having the ability to transfer or receive a charge from the analyte and an absorption of the wave length of the laser

* * *

For an infrared laser, aliphatic organic compounds, hydrocarbons, aliphatic organic compounds which contain heteroatoms such as oxygen nitrogen, sulfur, and combinations thereof, water and combinations of these compounds which can transfer to or receive a charge from the analyte are suitable. (Specification 11:1-8 – 8) (emphasis added)

Thus, the express definition of “Matrix” in the specification conveys to one skilled in the art that molecules of the liquid solution cause charge transfer that ionizes the analyte in solution without the need for any “additional matrix.”

B. The Negative Limitation “Without Additional Matrix” Need Not Be Written Verbatum in the Specification -- A Description of a Liquid Solution Containing Analyte is Sufficient.

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Applicants recognize that resolution of the pending written description issue depends on the instant specification, however, the present claims are copied from 6,683,300 and an analysis of the '300 specification should be relevant to the issue of the extent of disclosure necessary to satisfy the §112 written description requirement for the claim element that is common to the '300 patent and the present claims. The '300 patent has no verbatim disclosure of the phrase “without additional matrix...” and simply describes the same method of irradiating analyte in liquid solution as the present specification.

The method and system include the steps of or means for irradiating a liquid volume of the analyte solution with a light beam resulting in desorption of solution-specific ions into a surrounding gas to produce gas-phase ions, transferring the gas-phase ions to a mass, and mass-analyzing the gas-phase according to a mass to charge ratio.

'300 Patent, col. 4, lines 55 – 61

Ambient pressure ionization is achieved by irradiating the aqueous solutions with a pulsed laser at an absorption wavelength of the solution.

Id. at col. 5, lines 4 – 6

In accordance with the present invention, ions are produced at or about atmospheric pressure directly from an analyte solution which is deposited as a droplet from an atop of a solid target plate.

Id. at col. 5, lines 13 – 16

The analyte solution can include water, organic fluids, inorganic fluids, or a mixture thereof. The analyte solution can include solutions or organic and inorganic compounds including at least one of peptides, proteins, nucleic acids, polymers, drugs, and other compounds of biological, medical or industrial significance.

Id. at col. 6, lines 1 – 6

According to the present invention, the AP LADI method can be used for MS analyses of other liquid solutions such as the common analyte solutions previously discussed. The droplet size, laser pulse energy, and target plate material and/or coating are adjusted

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according to the present invention to optimize ionization efficiency for the type of solvent employed.

Id. at col.11, lines 4 – 9

The mass spectrometer interface according to the present invention can be modified so that a continuous flow of a liquid solution (e.g., from a high pressure liquid chromatography HPLC or capillary electrophoresis CE) is supplied directly to the laser spot position.

Id. at col. 11, lines 31 – 35

A liquid solution 38 that is to be mass-analyzed is supplied through a capillary transfer tube 37, connected at one end to a liquid pump such as for example a syringe pump, a liquid chromatography instrument pump, an output of capillary zone electrophoresis installation, or any other device that can provide a liquid analyte solution flow.

Id. at col. 11, lines 46 – 52

These examples show that the written support for the “without additional matrix added to said analyte solution” element in the ’300 patent was essentially the same as in the present specification. In both cases, the specification describes irradiation of analyte solution and the production of ions directly from the analyte solution. Therefore, the disclosure of this element in the present specification must be adequate to copy with written description requirement of §112.

CONCLUSION

Applicant submit that the support for the claim element at issue is more than sufficient to meet the standard of 35 U.S.C. §112 and that the pending claims recite patentable subject matter in common with USP 6,683,300.

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Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 150665.

Respectfully submitted,
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By: _____

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